K111972

JUL 27 2011

2 510(k) Summary

The following page contains the 510(k) Summary.

K111972

Medtronic

510(k) Summary

Date Prepared: July 6, 2011

Submitter: Medtronic
7611 Northland Drive
Minneapolis, MN 55428
Establish Registration Number: 2184009

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Device Name and Classification:

Product Family:	**Centrifugal Blood Pumps**
Trade Name:	Affinity Blood Pumps, Bio-Pumps
Common Name:	Centrifugal Blood Pump
Regulation Number:	870.4360
Product Code:	KFM
Classification:	Class III
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type

Product Family:	**MYOtherm Cardioplegia Delivery Systems**
Trade Name:	MYOtherm Cardioplegia Delivery Systems
Common Name:	Cardioplegia Delivery
Regulation Number:	870.4240
Product Code:	DTR
Classification:	Class II
Classification Name:	Heat-Exchanger, Cardiopulmonary Bypass

Product Family:	**Arterial Blood Filters**
Trade Name:	Affinity Arterial Filters
Common Name:	Arterial Blood Filters
Regulation Number:	870.4260
Product Code:	DTM
Classification:	Class II
Classification Name:	Filter, Blood, Cardiopulmonary Bypass, Arterial Line

Product Family:	**Oxygenators**

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Product Family:	**Oxygenators**
Trade Name:	Affinity NT Hollow Fiber Oxygenator with Plasma Resistant Fiber, Minimax Plus Oxygenator
Common Name:	Hollow Fiber Oxygenators
Regulation Number:	870.4350
Product Code:	DTZ
Classification:	Class II
Classification Name:	Oxygenator, Cardiopulmonary Bypass

Product Family:	**Cardiotomy/Venous Reservoirs**
Trade Name:	Affinity Cardiotomy/Venous Reservoirs
Common Name:	Cardiotomy/Venous Reservoir
Regulation Number:	870.4400
Product Code:	DTN
Classification:	Class II
Classification Name:	Reservoir, Blood, Cardiopulmonary Bypass

Product Family:	**Venous Reservoir Bags**
Trade Name:	MVR Collapsible Venous Reservoir Bag
Common Name:	Venous Reservoir Bag
Regulation Number:	870.4400
Product Code:	DTN
Classification:	Class II
Classification Name:	Reservoir, Blood, Cardiopulmonary Bypass

Product Family:	**Flow Probes**
Trade Name:	Bio-Probe Flow Probe
Common Name:	Flow Probe
Regulation Number:	870.2120
Product Code:	DPT
Classification:	Class II
Classification Name:	Probe, Blood-Flow, Extravascular

Product Family:	**Tri-Optic Measurement Cells**
Trade Name:	Tri-Optic Measurement Cells
Common Name:	Tri-Optic Measurement Cells
Regulation Number:	870.4330
Product Code:	DRY
Classification:	Class II
Classification Name:	Monitor, Blood-Gas, On-line, Cardiopulmonary Bypass

Product Family:	**Tubing and Connectors**

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Product Family:	**Tubing and Connectors**
Trade Name:	Extracorporeal Circuit Tubing and Connectors
Common Name:	Tubing and Connectors
Regulation Number:	870.4210
Product Code:	DWF
Classification:	Class II
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

Product Family:	**Resting Heart System**
Trade Name:	Resting Heart System
Common Name:	Low Prime Extracorporeal Circuit
Regulation Number:	870.4400 870.4290
Product Code:	DTN DTL
Classification:	Class II
Classification Name:	Reservoir, blood, Cardiopulmonary Bypass Adapter, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass

Product Family:	**Cardioplegia Adapters**
Trade Name:	DLP Cardioplegia Adapters
Common Name:	Cardioplegia Adapters
Regulation Number:	870.7290
Product Code:	DTL
Classification:	Class II
Classification Name:	Adapter, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass

Product Family:	**Aortic Root Cannula**
Trade Name:	DLP Aortic Root Cannula
Common Name:	Aortic Root Cannula
Regulation Number:	870.4210
Product Code:	DWF
Classification:	Class II
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

Product Family:	**Arterial Cannula**
Trade Name:	DLP, Select, EOPA Arterial Cannula
Common Name:	Arterial Return Cannula
Regulation Number:	870.4210
Product Code:	DWF
Classification:	Class II
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

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Product Family:	Venous Cannula
Trade Name:	DLP, MC2, MC2X, Single Stage, Two Stage, Three Stage Cannula
Common Name:	Venous Cannula
Regulation Number:	870.4210
Product Code:	DWF
Classification:	Class II
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

Product Family:	Femoral Cannula
Trade Name:	DLP and Bio-Medicus, Femoral Arterial and Femoral Venous Cannula
Common Name:	Femoral Cannula
Regulation Number:	870.4210
Product Code:	DWF
Classification:	Class II
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

Predicate Devices

Product Family:	Associated 510(k)s
Centrifugal Blood Pumps	K852807, K973011, K050109, K111658
MYOtherm Cardioplegia Delivery Systems	K003724, K011864
Arterial Blood Filters	K000379, K013084, K033468, K071253
Oxygenators	K933586, K973760, K000430
Cardiotomy/Venous Reservoirs	K926226, K936003, K021287
Venous Reservoir Bags	K920774
Flow Probes	K830858, K012747
Tri-Optic Measurement Cells	K910421, K012743
Tubing and Connectors	K891687, K902845, K012538
Resting Heart System	K031700
Cardioplegia Adapters	K790563, K790564, K791498, K841482, K850385
Aortic Root Cannula	K790565, K810548, K834039, K865079
Arterial Cannula	K840001, K840002, K031037, K031518, K033416, K043179, K061254

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Product Family:	Associated 510(k)s
Venous Cannula	K841275, K845045, K031776, K031827, K033264, K052372
Femoral Cannula	K872033, K875353, K884129, K915268, K924642, K052524

Device Description

No changes to the devices are being made. An additional source of the raw material used to make USP heparin used in Carmeda and Trillium coatings is being added.

Indications for Use

In general, these devices are intended for use during cardiopulmonary bypass surgery for up to 6 hours. No changes were made to the intended use of the individual devices.

Comparison to Predicate Devices

- Intended Use: All devices have the same intended use as their predicate devices.
- Principles of Operation and Technology: All devices have the same principle of operation and technology as their predicate devices
- Performance: Testing demonstrates that there is no coating performance difference between the two sources of raw material for heparin.
- Suppliers: The supplier of USP heparin remains the same. A new source of raw material is being added.

Summary of Performance Data

Bench testing was used to establish the interchangability of the two sources of raw material for USP heparin used in Carmeda and Trillium coating. Animal and human clinical testing was not required to establish substantial equivalence. The following performance tests were conducted:

- Coating testing
- Potency of Heparin
- Chemistry testing

Conclusion

Medtronic has demonstrated that the new source of raw material for heparin is interchangeable with the current source of raw material for heparin based upon testing results. Therefore, the Carmeda and Trillium coated devices are substantially equivalent to the existing, predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Perfusion System
c/o Ms. Jessica Sixberry
Senior Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, MN 55428

JUL 27 2011

Re: K111972
Affinity Blood Pumps, Bio-Pumps
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller type cardiopulmonary blood pump
Regulatory Class: Class III (three)
Product Code: KFM, DTR, DTM, DTZ, DTN, DPT, DRY, DWF, DTL
Dated: July 7, 2011
Received: July 11, 2011

Dear Ms. Sixberry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Statement of Indications for Use

The following page contains a representative 'indications for use' statement from each of the associated families that are included in this change. The following is a list of the associated families of Medtronic devices:

- Centrifugal Blood Pumps
- MYOtherm Cardioplegia Delivery Systems
- Arterial Blood Filters
- Oxygenators
- Cardiotomy/Venous Reservoirs
- Venous Reservoir Bags
- Flow Probes
- Tri-Optic Measurement Cells
- Tubing and Connectors
- Resting Heart System
- Cardioplegia Adapters
- Aortic Root Cannula
- Arterial Cannula
- Venous Cannula
- Femoral Cannula

510(k) Number (if known): K111972

Device Name: Affinity CP Centrifugal Blood Pump

Indications for Use: The Affinity CP Centrifugal Blood Pump with Carmeda BioActive Surface is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours).

It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring completecardiopulmonary bypass (eg, valvuloplasty, circulatory support during mitral valve reoperation, surgery of the
vena cava or aorta, liver transplants).

Prescription Use __X__ OR Over-The-Counter Use _____
Per 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111972

Device Name: Medtronic MYOtherm XP, Cardioplegia Delivery System

Indications for Use: The MYOtherm XP® is a device intended for the mixing, warming/ cooling and delivery of oxygenated blood/cardioplegia solution in a predetermined ratio.

Device Name: Affinity Arterial Filter

Indications for Use: The Affinity Arterial Filter is indicated for use in cardiopulmonary bypass procedures up to 6 hours in duration for the removal of particulate and gaseous microemboli.

Device Name: Affinity Hollow Fiber Oxygenator with Plasma Resistant Fiber

Indications for Use: The Affinity NT Hollow Fiber Oxygenator with Plasma Resistant Fiber is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Device Name: Affinity NT Integrated CVR Membrane Oxygenator

Indications for Use: The AFFINITY® NT Integrated CVR Membrane Oxygenator (Plasma Resistant Fiber [PRF] Oxygenator) is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Device Name: MVR Collapsible Venous Reservoir Bag

Indications for Use: This product, is indicated for use during cardiopulmonary bypass surgery in an extracorporeal circuit utilizing a membrane oxygenator. The MVR® Holder (Model MVR-SH) is indicated for use with the MVR® Collapsible Venous Reservoir Bag.

Device Name: Medtronic Coated Accessories (Flow Probes)

Indications for Use: This product is indicated for use in the extracorporeal circuit during cardiopulmonary bypass surgery.

Device Name: Medtronic Coated Accessories (Tri-Optic Measurement Cells)

Indications for Use: This product is indicated for use in the extracorporeal circuit during cardiopulmonary bypass surgery.

Device Name: Medtronic Packs and Accessories (Tubing and Connectors)

Indications for Use: This product is indicated for use in the extracorporeal circuit during cardiopulmonary bypass surgery.

Device Name: Medtronic Resting Heart System

Indications for Use: The Medtronic® Resting Heart™ Module is indicated for use in surgical procedures requiring extracorporeal circulatory support, gas exchange, and thermal regulation. The device is indicated for use in procedures requiring blood flow rate of 1-6 lpm and lasting up to six hours. The system is indicated for use only with the Bio-Console®. The VARD is indicated for use only with the AAR1000. The Bio-Pump+® Blood Pump in the Medtronic® Resting Heart™ Module is indicated for use only with the Bio-Console®. The Carmeda® AFFINITY® NT Oxygenator and Carmeda® AFFINITY® Arterial Filter in the Medtronic® Resting Heart™ Module have the same indications for use as a Carmeda® AFFINITY® NT Oxygenator and Carmeda® AFFINITY® Arterial Filter used in other extracorporeal circuits.

Device Name: Medtronic DLP "Y" Adapter – Coronary Perfusion

Indications for Use: This adapter is intended for use in conjunction with the delivery of cardioplegia solution.

Device Name: Medtronic DLP Aortic Root Cannula

Indications for Use: This cannula is intended for use in conjunction with cardiopulmonary bypass surgery for delivering cardioplegia solution. The cannula may also be used to aspirate air from the aorta at the conclusion of the bypass procedure. The #23009 cannula may also be used to monitor pressure in the aorta.

Device Name: Medtronic EOPA 3D Arterial Cannula

Indications for Use: These cannulae are intended for use in perfusion of the ascending aorta during short term (6 hours or less) cardiopulmonary bypass.

Device Name: Medtronic DLP Single Stage Venous Cannula

Indications for Use: These cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.

Device Name: Medtronic DLP Femoral Arterial and Venous Cannula

Indications for Use: This cannula is intended for rapid femoral venous and arterial access for short term cardiopulmonary bypass.